

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

SHIRE LABORATORIES INC.,)	
)	Case No. 08-cv-1367
Plaintiff,)	Judge: Ruben Castillo
)	
v.)	(Related Case No. 06-cv-2266) (SRC) (MAS)
)	(D.N.J.)
COREPHARMA LLC,)	
Defendant.)	

**DEFENDANT COREPHARMA'S OPPOSITION TO PLAINTIFF SHIRE'S MOTION
TO COMPEL THE PRODUCTION OF DOCUMENTS AND DISCOVERY FROM NON-
PARTIES PHARMPRO AND DON VERBARG**

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I. INTRODUCTION

Shire seeks by its motion to compel discovery from non-parties, PharmPro division of FluidAir and its officer, Don Verbarg, in violation of an order of the court in which this case is pending, the United States District Court for the District of New Jersey (the “forum court”). The order was entered on December 27, 2007 and provides that “Fact discovery is to remain open through January 31, 2008”. (Third Amended Pretrial Scheduling Order at 2, ¶1) (copy attached, Exhibit A). On February 1, 2008, after discovery had closed by the terms of the forum court’s scheduling order, Shire applied to the forum court for “permission to complete [the PharmPro depositions and document production] after the January 31st deadline.” (Letter, February 1, 2008 from Shire’s counsel to U.S.M.J. Michael A. Shipp, D.N.J., Exhibit 9 to Shire’s motion). Defendant Corepharma opposed that application (See Letters dated February 1 and 5, 2008 from Corepharma’s counsel to the forum court, Exhibit B, attached). The forum court has not granted Shire the extension it sought. Further, Shire waited until March 7, 2008, more than a month after the close of fact discovery and more than a month after its unsuccessful application to extend the discovery cutoff date, to make its present motion, which is therefore untimely. The subpoenas Shire seeks to enforce by its motion are unenforceable, as they demand document production and appearance by Illinois residents in New York. Finally, the discovery Shire seeks by its motion is irrelevant to any issue in the patent infringement action in which they were issued. The Court should deny Shire’s motion.

II. FACTS

A. NATURE OF THIS ACTION

Shire brought this patent infringement action under the Hatch-Waxman Amendments to the Patent Act and the Food, Drug and Cosmetics Act. Under Hatch-Waxman, a generic drug

company may submit an Abbreviated New Drug Application (ANDA) to the Food and Drug Administration for permission to market a generic version of a brand name drug without conducting the clinical trials that would otherwise be required. The purpose of the act is to provide for expedited introduction of generic drugs, which tend to be less expensive than brand name drugs. If the brand name company has represented to FDA that its drug is covered by a U.S. Patent, the filing of the ANDA is “a highly artificial act of infringement”, *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990) which confers subject matter jurisdiction on district courts to determine before any actual infringement has occurred whether, if marketed, the proposed generic drug would infringe the brand name company’s patent. By filing suit against the generic company the brand name company gets the benefit of an automatic 30-month delay in FDA’s approval of the generic company’s application. 21 U.S.C. § 355(j)(5)(B)(iii).

The Hatch-Waxman provisions permit the forum court to determine whether Corepharma’s proposed generic carbamazepine capsules will infringe Shire’s patent before Corepharma’s product is ever marketed. Accordingly, the issue of infringement is determined by comparing the proposed product, as described in Corepharma’s ANDA, with the claims in Shire’s ‘570 patent. *Bayer AG v. Elan Pharmaceutical Research Corp.*, 212 F.3d 1241, 1248-1249 (Fed. Cir. 2000); *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997); *Bristol-Myers Squibb Co. v. Royce Lab.*, 69 F.3d 1130, 1135 (1995).

In this case, Corepharma submitted an ANDA to the FDA seeking permission to market a generic version of Shire’s Carbatrol® capsules, containing the active ingredient carbamazepine, which is used in the treatment of epilepsy and certain types of pain. Shire sued Corepharma for infringing two patents, its U.S. Patent Nos. 5,326,570 (‘570 patent) and 5,912,013 (‘013 patent), thus obtaining the benefit of the automatic 30-month stay of approval of Corepharma’s

application. Shire withdrew its claim of infringement under the '013 patent with prejudice and is proceeding in the forum court on its claim that Corepharma's ANDA product will infringe the '570 patent, which covers pharmaceutical products or use of those products to treat patients. The '570 patent does not cover the manufacture of the pharmaceutical products. See, '570 patent, claims 1-25 (column 8, line 1 through column 10, line 11).

B. PROCEDURAL HISTORY

In April 2006, before Shire started this lawsuit, Corepharma provided Shire with confidential access to the pertinent portions of its ANDA and samples of the ANDA product, as provided in 21 U.S.C. §355(j)(5)(C)(i)(III). (See, Letter dated April 25, 2006 from Corepharma to Shire, Exhibit C, attached). The parts of the ANDA which Corepharma produced identified PharmPro as a contract manufacturer which was to carry out certain of the steps in the manufacture of Corepharma's proposed generic version of Shire's Carbatrol®. On July 12, 2007, in discovery under the then-current scheduling order, Corepharma produced additional documents which provided further details of what PharmPro was to do, including correspondence with PharmPro. As a result, when Shire examined Corepharma witnesses at deposition, Shire asked them about PharmPro and Mr. Verbarg and their role in the manufacture of Corepharma's proposed generic product. (See, e.g., Exhibit 2 to Shire's motion, excerpts from the deposition of M. Gande, the Corepharma officer who dealt most directly with PharmPro).

Despite having ample knowledge of PharmPro and Mr. Verbarg and their role in the Corepharma product, Shire made no effort to obtain discovery from PharmPro, or Mr. Verbarg, at any time in 2006 or in 2007, even though the extant scheduling orders provided for fact discovery to be completed by December 31, 2007. Toward the end of December, 2007 the

parties stipulated to a brief amendment to the scheduling order which extended the fact discovery period to January 31, 2008. (See the forum court's Scheduling Order, Exhibit A, attached).

It was not until January 7, 2008 that Shire first made any effort to obtain any discovery from PharmPro or Mr. Verbarg. It served subpoenas on them that day, issued from this Court. But the subpoenas required PharmPro and Mr. Verbarg to appear for deposition at the offices of Shire's lawyers in New York City, and to produce documents in New York City in advance of the depositions. (Exhibits 3 and 4 to Shire's motion).¹

On January 11, 2008, four days after the subpoenas were served, PharmPro's and Mr. Verbarg's attorney served timely written objections to the subpoenas under Fed.R.Civ.P. 45 (c) (1) (B) and 45 (e). In addition to objecting to the subpoenas demands that PharmPro and Mr. Verbarg appear in New York City, PharmPro and Mr. Verbarg objected that the subpoenas were overly broad and burdensome and would require production of confidential, proprietary trade secrets and confidential business information. Shire never issued and served new subpoenas providing for PharmPro and Mr. Verbarg to appear and produce documents in this District and it is the original subpoenas, with their unenforceable demands for production and appearance in New York City, which Shire seeks to enforce in its present motion.

Mr. Bullwinkel and Shire's counsel engaged in some correspondence concerning the subpoenas, without resolution. January 31, 2008, the date by which the forum court had ordered

¹ In December, 2007 Corepharma had noticed the deposition of a Shire witness, Dr. Couch. It was not until January 17, 2008 that Shire advised Corepharma's counsel that Dr. Couch would not be made available for deposition until February 15, 2008. As Corepharma explained to Magistrate Judge Shipp of the District of New Jersey in its letter of February 1, 2008 (Exhibit B, attached), Shire confirmed that Dr. Couch would appear for deposition on February 15 and, under the circumstances, Corepharma's counsel saw no useful purpose in moving to compel his appearance before that date. Dr. Couch appeared and his deposition was taken on February 15.

all fact discovery to be completed, came and went. Shire had made no effort to enforce the subpoenas or to extend the fact discovery period under the forum court's Scheduling Order.

It was not until February 1, 2008, after fact discovery had already closed pursuant to the forum court's Scheduling Order, that Shire first requested that the forum court extend the fact discovery period to accommodate the discovery Shire sought under the subpoenas to PharmPro and Mr. Verbarg. As noted above, the forum court has not granted Shire's request. Shire then waited another month, until March 7, 2008, to move to compel production under its January 7 subpoenas to PharmPro and Mr. Verbarg.

III. ARGUMENT

A. THE DISCOVERY SHIRE SEEKS IS BARRED BY THE FORUM COURT'S SCHEDULING ORDER

The Scheduling Order in the District of New Jersey, the court in which this lawsuit is pending and will be decided, required the parties to complete their fact discovery by January 31, 2008. The forum court has not granted Shire's application to extend that date to allow Shire time to conduct the discovery demanded in its subpoenas. This Court should not abrogate the forum court's Scheduling Order by permitting Shire to obtain discovery by subpoena which the Scheduling Order bars. In *Garvin v. Southern States Insurance Exchange Co.*, No. 1:04cv73, 2007 U.S. Dist. LEXIS 63664, *14 (N.D.W.Va. Aug. 28, 2007) the court quashed a subpoena to non-parties "[b]ecause Plaintiffs' subpoena duces tecum to the non-parties ... is a discovery tool and could not be completed prior to the close of discovery under the Court's Order and because no extension of that discovery cut-off date was obtained and there was no stipulation to extend the discovery deadlines". See, also, *Cincinnati Insurance Co. v. Cochran*, No. 5:05cv93, 2005 U.S. Dist. LEXIS 44806, *12, n.6 (N.D. Fl. Sept. 22, 2005), in which the court from which the subpoena to a non-party had issued denied a motion to compel discovery under the subpoena,

inter alia, because, under the “scheduling order entered by the District Court [where the action was pending], the discovery deadline had already passed” and the issuing court “should not extend the discovery deadline imposed by another court where the action was pending ...”. Nor was amendment of the subpoena to correct its other defects allowed unless and until the forum court granted such an extension of the deadline. *Id.*

Shire offers no excuse for its failure to seek the discovery its subpoenas would require of PharmPro and Mr. Verbarg in 2006 or 2007, despite its receipt and review of documents during those years providing Shire ample knowledge of PharmPro’s role in the manufacture of Corepharma’s proposed product. Shire plainly had such knowledge long before it issued its subpoenas; it questioned Corepharma’s witness M. Gande about PharmPro at deposition based on the documents Corepharma had produced.

B. SHIRE’S SUBPOENAS ARE DEFECTIVE

Shire’s subpoenas required PharmPro and Mr. Verbarg to appear for deposition, and to produce documents in New York City, even though the subpoenas issued from this Court and even though New York is “more than 100 miles from where [PharmPro or Mr. Verbarg] resides, is employed, or regularly transacts business in person”. Fed.R.Civ.P. 45(c)(3)(A)(ii). The subpoenas are invalid and unenforceable as written. *Cincinnati Insurance*, 2005 U.S. Dist. LEXIS 44806, at *12 (quashing subpoena which required appearance and production of documents outside the state in which the issuing district court was located under Rule 45 (c) (3) (A) (ii)) and cases cited in that decision.

1. It is Too Late for Shire to Cure the Defects in its Subpoenas

Upon receipt of PharmPro’s and Mr. Verbarg’s objections, Shire could have issued new subpoenas curing the invalidity of those it had originally served, but it chose not to. With the expiration of the fact discovery period under the forum court’s Scheduling Order, Shire’s time to

issue new subpoenas or to amend the original subpoenas to cure their defects, has also expired.

Id. at n.6.

C. THE DISCOVERY SHIRE SEEKS IS IRRELEVANT TO THE CLAIMS OF DEFENSES OF ANY PARTY

As described above, Shire's '570 subpoena covers "a drug delivery system for the oral administration of carbamazepine" ('570 patent, claims 1-17) and "a method of treating a patient with carbamazepine by administering to said patient a composition which contains ..." (claims 18-25). No claim in the patent covers manufacture of the "drug delivery system" or "composition". Yet PharmPro's role in Corepharma's product is limited to steps which are part of the process for manufacturing Corepharma's proposed generic product. PharmPro's and Mr. Verbarq's lawyer pointed this discrepancy out in an email to Shire's counsel on January 24, 2008 (Exhibit 10 to Shire's motion), reminding him, correctly, that the '570 patent "claims nothing about how the API [active pharmaceutical ingredient] is processed into capsules, which is the only thing that PharmPro did for Corepharm." Whatever the manufacturing process for the API is, nothing in the Shire patent covers it, and Corepharma's performance of part of that process is therefore irrelevant.

In addition, because this is a Hatch-Waxman case, which relates to an application by Corepharma to market a product in the future, the description of that product in Corepharma's ANDA and the samples of the product Corepharma produced to Shire are the only things which the forum court is required to consider in determining whether the product, if and when it is marketed, would infringe Shire's patent. *See Bayer*, 212 F.3d at 1248-49; *Glaxo*, 110 F.3d at 1569; *Bristol-Myers Squibb*, 69 F.3d at 1135. The steps in the manufacturing process which PharmPro performed are irrelevant.

CONCLUSION

The Court should deny Shire's motion to compel.

Respectfully submitted,

Dated this 26th day of March, 2008.

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on March 26, 2008, a true and correct copy of the foregoing DEFENDANT COREPHARMA'S OPPOSITION TO PLAINTIFF SHIRE'S MOTION TO COMPEL THE PRODUCTION OF DOCUMENTS AND DISCOVERY FROM NON-PARTIES PHARMPRO AND DON VERBARG was filed electronically with the Clerk of Court using the CM/ECF System, which will provide electronic notice to the following:

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